Healthcare (USA) Inc.

2420 Carson Street · Suite 125 · Torrance, CA 90501

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JAN 2 2 2002

SUMMARY PREMARKET 510(k) NOTIFICATION
For UniGlove Lano-E Powder-Free Latex Examination Gloves
510(k) Number: K013163

Submission Applicant:

N.S. Uni-Gloves Sdn. Bhd.
Lot 3 & 4/4510 Senawang Industrial Estate,
70450 Seremban, Negeri Sembilan
Malaysia
Telephone No. 60-6-677-2751/2
Fax No. 60-6-677-2755

Registration No. **8040880** Devise Listing No. **B 034616**
510(k) Number: _____

Official Correspondent in the United States:

Robert D. Vander Leek, President
UG Healthcare (USA) Inc.
2420 Carson St., Suite 125
Torrance, CA 90501

Telephone No.: (310) 328-7981
Fax No.: (310) 328-7829

Submitted: September 14, 2001

A. Description of the Device
Trade Name: UniGlove Lano-E Powder-Free Latex Examination Glove
Common Name: Examination Gloves
Classification Name: Patient Examination Glove (per 21 CFR 880.6251)
Class I Powder-Free Latex examination glove 80LYY that meets all of the requirements of ASTM Standard D 3578 – 00

Intended Use of the Device: A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between the patient and the examiner.

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Summary of Technological Characteristics:
Material: Latex **Cuff:** Beaded **Powder Residue:** Maximum 2mg/glove
Quality Assurance: In compliance with ASTM D3578-00, EN 455-2 : 1995, EN 455-1 : 1993, ISO 2859-1:1989 and manufactured under GMP.

Inspection Parameters:

Criteria	Inspection Level	AQL
Dimensions	S-2	4.0
Physical Properties	S-2	4.0
Water Tight Test 1000ml	G-1	1.5
Visual Major Defects	G-1	1.5
Visual Minor Defects	G-1	2.5

Physical Properties:

Dimensions:

Overall Length:	240 mm minimum
Width:	95 mm minimum (for medium glove)
Palm Thickness:	0.15 to 0.20 mm (at center of palm)
Finger Thickness:	0.17 to 0.25 mm (at 15mm from tip of center finger)
Cuff Thickness:	0.10 to 0.15 mm (at 40mm from the beaded end)

	BEFORE AGING	AFTER AGING
Tensile Strength:	21. Mpa minimum	16.0 Mpa minimum
Ultimate Elongation:	700% minimum	500% minimum
Pinhole AQL	1.5 minimum	1.5 minimum

Special Properties: Processed with pharmaceutical quality lanolin as the emollient and conditioning agent. Also contains Vitamin E which complies with the current USP, Ph.Eur., DAB and BP monographs.

Packaging: 100 pcs per dispenser box, 10 boxes per case, 1,000 gloves per case

Conclusion: The UniGlove Powder-Free Latex Examination Glove meets the physical property requirements of ASTM D 3578-00 and the FDA 1000 ml water test both before and after aging.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 2 2002

N.S. Uni-Gloves Sdn. Bhd.
C/O Robert D. Vander Leek
UG Healthcare (USA), Incorporated
2420 Carson Street, Suite 125
Torrence, California 90501

Re: K013163
Trade/Device Name: UniGlove Lano-E Powder-Free Latex Examination Gloves with Protein Content Labeling Claim (50 Micrograms or Less)
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: January 8, 2002
Received: January 9, 2002

Dear Mr. Leek:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013163

Device Name: **UNIGLOVE LANO-E POWDER-FREE EXAMINATION GLOVES WITH PROTEIN LABELING CLAIM (50 MICROGRAMS OR LESS)**

Indications For Use:

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___ OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
510(k) Number K013163